

Health Alert
March 26, 2004

Health Alert:

Expanded Recall
of a Nasal Spray
Contaminated with
Burkholderia cepacia
Complex

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This document will be updated as new information becomes available. The current version can always be viewed at <http://www.dhss.state.mo.us/>.

The Missouri Department of Health & Senior Services (DHSS) is now using 4 types of documents to provide important information to medical and public health professionals, and to other interested persons:

Health Alerts convey information of the highest level of importance which warrants immediate action or attention from Missouri health providers, emergency responders, public health agencies, and/or the public.

Health Advisories provide important information for a specific incident or situation, including that impacting neighboring states; may not require immediate action.

Health Guidances contain comprehensive information pertaining to a particular disease or condition, and include recommendations, guidelines, etc. endorsed by DHSS.

Health Updates provide new or updated information on an incident or situation; can also provide information to update a previously sent Health Alert, Health Advisory, or Health Guidance; unlikely to require immediate action.

Office of the Director
912 Wildwood
P.O. Box 570
Jefferson City, MO 65102
Telephone: (800) 392-0272
Fax: (573) 751-6041
Web site: www.dhss.state.mo.us

FROM: RICHARD C. DUNN
DIRECTOR
SUBJECT: **Expanded Recall of a Nasal Spray Contaminated with**
***Burkholderia cepacia* Complex**

There has been an expanded recall of an oxymetazoline HCL 0.05% nasal spray because of intrinsic contamination with *Burkholderia cepacia* complex. The nasal spray is available over the counter and is labeled "Major Soothing Twice-A-Day 12 Hour Nasal Spray Decongestant Regular Oxymetazoline Hydrochloride 0.05%. Distributed by Major Pharmaceuticals, Livonia, MI". Patients with weakened immune systems or chronic lung diseases, particularly cystic fibrosis (CF), may be at increased risk for severe infections with *B. cepacia* complex.

Last week the manufacturer, Propharma Inc., recalled lot number K4496. Preliminary molecular epidemiology had indicated that isolates related to the strain found in the nasal spray had been recovered from patients in multiple states. Today, the recall was expanded to include additional lots. The lot numbers now being recalled are E4410, F4433, H4464, K4496, L4529, L4535, M4536, A4558, A4588, and B4597. **The lot number can be found on the bottom of the carton and on the back of the bottle label.** (See the company press release on the Food and Drug Administration (FDA) web site at http://www.fda.gov/oc/po/firmrecalls/major03_04.html.)

The Centers for Disease Control and Prevention (CDC) is currently assisting the state of Missouri, investigating several cases of *B. cepacia* that have been identified in one hospital, to examine the impact of the recalled product on patient safety and the potential spread of *B. cepacia* within the healthcare setting.

B. cepacia is a multidrug-resistant organism and management of patients with these bacteria should be in accordance with hospital policy for infection control and isolation precautions. *B. cepacia* poses very little medical risks to healthy people; however, people whose health is otherwise compromised may be more susceptible. If individuals have used this product and are concerned they should contact their healthcare provider.

B. cepacia consists of several species, or a complex, of bacteria, that are found in the natural environment. Some of these species threaten the health of individuals with cystic fibrosis (CF). It is important to note that in general, the species that colonize the lungs of people with CF differ from most of those found in the natural environment. However, all species of *B. cepacia* have been recovered from the sputum of people with CF; these bacteria were only first reported in people with CF in the 1970s.

B. cepacia bacteria are able to survive in the environment or in the lungs of a person with CF. They are resistant to most common cleaning disinfectants and to many antibiotics, which makes them difficult to treat once they infect the lungs. However, some species may be successfully treated with combinations of antibiotics. Standard health precautions greatly reduce the risk of infection.

Cases of *B. cepacia* complex infection or colonization associated with use of the recalled product should be reported to the local public health agency, or to the Missouri Department of Health and Senior Services (DHSS) at 800/392-0272. If a medical laboratory isolates an organism believed to be *B. cepacia*, the isolate can be sent to the Missouri State Public Health Laboratory for confirmation.

Questions should be directed to DHSS's Disease Investigation Unit at 573/751-6268.

